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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/617,895

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Ryan P. Boucher

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08/11/2010

Medtronic

Attn: Noreen C. Johnson, IP Legal Department

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

08/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/617,895	Applicant(s) BOUCHER ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-18 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/9/10; 3/24/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 02/09/2010.

The examiner acknowledges the amendments made to the claims.

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 02/09/2010 and 03/24/2010 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

2. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitation of the catheter body having an open distal end configured to prevent movement of the stylet therethrough in claim 6 is also evident in the last two lines of claim 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-9 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Fogarty et al.** (U.S. Patent No. **4,483,340**) in view of **Moutafis et al.** (U.S. Patent No. **5,090,957**).

In regards to claims 1-2, 4, and 12 Fogarty et al. disclose a catheter body **24** defining an interior lumen (within **24**), an expandable structure **20** having a distal end and carried by the catheter body and a substantially rigid stylet **30** having a proximal end and being sized and configured for passage through the lumen and adapted to straighten the expandable structure during deployment into an interior body region, the stylet being selectively insertable into and withdrawable from an interior of the expandable structure via the interior lumen (Figures 1-4). The catheter body defines a distal end opening **34** through which a substance may be flowed outwardly from the interior lumen into an interior body portion (encased by **22**). The distal end opening also prevents outward movement of the stylet therethrough.

In regards to claims 5 and 14-15, the proximal end **36** of the stylet is coupleable to the catheter tube assembly and it abuts against the distal end **22** of the expandable structure (Figure 4).

In regards to claim 6, the catheter body has an open distal end **22** configured to prevent movement of the stylet therethrough.

In regards to claims 7-8 the catheter tube assembly includes an outer elongate body **14** and an inner elongate body **24**, wherein the expandable structure **20** has a proximal end that is coupled to a distal end of the outer elongated body **14** and a distal end coupled to a distal end **22** of the inner elongated body (Figures 3-4).

In regards to claim 9, an outer body lumen (between **14** and **24**) is in fluid communication with the lumen of the expandable structure such that insertion of a filling material (fluid) into the outer body lumen passes into the lumen of the expandable structure to expand the expandable structure (Figure 3).

Forgarty et al. do not disclose the distal end opening through which a substance may be flowed outwardly from the interior lumen into an interior body portion.

Moutafis et al. teach a similar distal end **230** of a catheter body having an opening **236a** through which a substance may be flowed outwardly from an interior lumen into an interior body portion (Figures 3A-3B), while still preventing movement of a stylet **214** or **240** therethrough. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a distal end opening through which a substance may be flowed outwardly, as taught by Moutafis et al., in order to facilitate delivery of fluids in the delivery site (col. 2, lines 39-50).

In regards to claims 3 and 13 Fogarty et al. also do not expressly disclose the stylet being made of stainless steel. However, Moutafis et al. teach a stainless tube stylet (col. 4, lines 1-3) and it would have been obvious to one having ordinary skill in

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the art at the time the invention was made to modify the substantially rigid stylet of Fogarty et al. by making it from stainless steel material, as taught by Moutafis et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.

5. Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vargas, III** (U.S. Patent No. **5,468,245**) in view of **Fogarty et al.** (U.S. Patent No. **4,483,340**) and **Moutafis et al.** (U.S. Patent No. **5,090,957**).

Vargas, III discloses a catheter body defining an elongated outer body **8** and an elongated inner body **2**, an expandable structure **1** being disposed on a distal portion of both the outer and inner body (Figure 1), the expandable structure having sufficient strength to compact cancellous bone, a filling material comprising bone cement **A** which is flowable through the outer body lumen into the expandable structure for expansion of the expandable structure (Figure 16). The inner elongated body has an open distal end in communication with an inner body lumen such that a substance passes through the inner body lumen and is discharged through the distal opening (Figures 25-26).

Vargas, III lacks a stylet having a proximal end and being sized and shaped for passage through the inner body lumen and adapted to straighten the expandable structure during deployment and the inner body having an open distal end allowing introduction of a substance therethrough while preventing movement of the stylet outwardly therethrough.

Fogarty et al. teach a stylet **30** adapted to straighten an expandable structure **20** during deployment into an interior body region, the stylet being selectively insertable into and withdrawable from an interior of the expandable structure via the lumen (Figures 1-4).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the expandable structure **1** of Vargas, III by having a stylet that is selectively engageable to a portion thereof, as taught by Fogarty et al., in order to selectively straighten and reduce the profile of the expandable structure of Vargas, III during deployment and withdrawal.

Moutafis et al. teach a distal end **230** of a catheter body having an opening **236a** through which a substance may be flowed outwardly from an interior lumen into an interior body portion (Figures 3A-3B), while still preventing movement of a stylet **214** or **240** therethrough. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a distal end opening through which a substance may be flowed outwardly in Vargas, III, as taught by Moutafis et al., in order to facilitate delivery of fluids in the delivery site (col. 2, lines 39-50) while still allowing engagement with a stylet.

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6. Claims 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vargas, III** (U.S. Patent No. **5,468,245**) in view of **Fogarty et al.** (U.S. Patent No. **4,483,340**).

Vargas, III discloses a catheter body defining an outer body **8** and an inner body **2**, an expandable structure **1** being disposed on a distal portion of both the outer and inner body (Figure 1), the expandable structure having sufficient strength to compact cancellous bone, a filling material comprising bone cement **A** which is flowable through the outer body lumen into the expandable structure for expansion of the expandable structure (Figure 16). The radially expandable structure **1** expands to a predetermined desired profile within bone and has a first expandable segment (proximal to taper near **2**, see Figure 24) having a larger radius than a second expandable segment (taper near **2**) and having a joining segment joining the first and second segments, as seen in Figures 20-24, and having a “generally spherical shape.”

Vargas, III lacks a stylet having a proximal end and being sized and shaped for passage through the inner body lumen and adapted to straighten the expandable structure during deployment.

Fogarty et al. teach a stylet **30** adapted to straighten an expandable structure **20** during deployment into an interior body region, the stylet being selectively insertable into and withdrawable from an interior of the expandable structure via the lumen (Figures 1-4).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the expandable structure **1** of Vargas, III by having a stylet that is

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selectively engageable to a portion thereof, as taught by Fogarty et al., in order to selectively straighten and reduce the profile of the expandable structure of Vargas, III during deployment and withdrawal.

Response to Arguments

7. Applicant's arguments with respect to claims 1-10, 12-18, 20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734